



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,688	02/10/2004	Gregory B. Altshuler	105090-0232	3815
21125 7590 07/31/2008 NUTTER MCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER JOHNSON III, HENRY M	
			ART UNIT 3739	PAPER NUMBER
			NOTIFICATION DATE 07/31/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com

Office Action Summary

Application No.

10/776,688

Applicant(s)

ALTSHULER ET AL.

Examiner

Henry M. Johnson, III

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 6, 9, 10, 15-20, 22-24, 26-30 and 48-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 9, 10, 15-17, 19, 20, 22-24, 26-30 and 48-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Final Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Response to Arguments

Applicant's arguments filed June 6, 2008 with respect to the rejection(s) of claim(s) 1-3, 5, 6, 8, 10, 13, 15-17, 20, 22, 26-29 and 48-51 under 35 U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of U.S. Patent 6,159,236 to Biel in view of U.S. Patent Application Publication US 2002/0183808 to Biel.

The main manipulative steps claimed are inserting an applicator into an oral cavity and irradiating tissue in the oral cavity. A reference that provides such steps inherently would irradiate any endogenous acceptors as, by definition, they are present and having irradiated the acceptors the same result would occur. A reference need not specifically cite a specific result or target if such would occur with the method steps cited. Where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

Regarding claims 27 and 52, the exposing all of a patient's blood to the radiation, no specific manipulative steps for accomplishing such exposure are claimed. Therefore, since Biel teaches the steps cited, the exposure would be accomplished.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 6, 9, 10, 15-17, 19, 48, 49 and 52 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

Art Unit: 3739

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specific power intensity of 0.35 W/cm^2 to 10 W/cm^2 is new matter not in the original disclosure. Narrowing of a range to overcome an art rejection falls under the new matter rejection. The narrowed range must have been previously disclosed.

Exposing an entire volume of blood in a single treatment is new matter. Prior disclosure allowed such exposure in more than a single treatment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 6, 8-10, 13, 15-17, 20, 22, 26-30 and 48-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,159,236 to Biel (Biel '236) in view of U.S. Patent Application Publication US 2002/0183808 to Biel (Biel '3808). Biel '236 discloses a

method of using a light emitting treatment device in a body, comprising positioning the member to direct light at the treatment site and activating the light source for a period of time to emit energy at the treatment site for photodynamic therapy. Viruses, fungi and bacteria are specifically targeted (abstract). The one or more light sources are configured to provide light wavelengths ranging from about 450 nanometers to about 850 nanometers, a light dosage rate ranging from about 0 mW/cm² to about 150 mW/cm² and a light dose ranging from 0 J/cm² to about 300 J/cm² (Col. 2, line 66 to Col 3, line 11). The wavelengths overlap those disclosed by the applicant as being absorbed by endogenous agents. Biel '236 teaches selecting the wavelength based on the target agent. Independent claim 13 of Biel '236 has no step of introducing any exogenous agent, thus implying an endogenous target. The radiation of pathogens would inherently produce the same results as those claimed. The body cavity may be an oral cavity (Fig. 4). Times within the cited treatment times are inherent to achieve the fluence disclosed by Biel with the powers disclosed. As noted above, PDT only requires light absorption by an agent or chromophore without limitation as to its being exogenous or endogenous. Biel '236 does not disclose power intensities of from 0.35 W/cm² to 10 W/cm². Biel '3808 teaches irradiation with a power of 0.4 W/cm² to treat pathogens in an oral cavity. It would have been obvious to one skilled in the art to use the intensity as taught by Biel '3808 in the method of Biel '236 as they both are irradiating for the same result.

The main manipulative steps claimed are inserting an applicator into an oral cavity and irradiating tissue in the oral cavity. A reference that provides such steps inherently would irradiate any endogenous acceptors as, by definition, they are present and having irradiated the acceptors the same result would occur. A reference need not specifically cite a specific result or target if such would occur with the method steps cited. Where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the

Art Unit: 3739

reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

Regarding claims 2, 3, 5 and 50-51, no method steps are associated with the location of the light receptors or a specific light receptor or a specific pathogen. To be further limiting, a further step is required.

Regarding claims 8 and 28, the fluences of Biel are within the range of the Applicant for killing pathogens.

Regarding claims 9 and 30, no specific manipulative steps are claimed that would lead to specific target acceptors.

Regarding claim 10, no step impacts how the receptor responds to non-visible light.

Regarding claims 27 and 52, no specific manipulative steps for accomplishing such exposure are cited. Therefore, since Biel teaches the steps cited, the exposure would be accomplished.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,159,236 to Biel (Biel '236) in view of U.S. Patent Application Publication US 2002/0183808 to Biel (Biel '3808) as applied to claim 1 above, and further in view of U.S. Patent 6,135,774 to Hack et al. Biel '236 and Biel '3808 are discussed above, but do not teach the use of diagnostic signals. Hack et al. teach a device for detecting fluorescence from teeth that may be used as a measure of whiteness thus providing a teaching of diagnostic feedback during the oral application of light radiation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use diagnostic feedback as taught by Hack et al. in the method of Biel '236 in view of Biel '3808 as feedback during a light treatment process is well known and obvious.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,159,236 to Biel (Biel '236) in view of U.S. Patent Application Publication US

Art Unit: 3739

2002/0183808 to Biel (Biel '3808) as applied to claim 20 above, and further in view of U.S. Patent 6,026,828 to Altshuler. Biel '236 and Biel '3808 are discussed above, but do not teach wavelengths below 450 nanometers. Altshuler teaches a device for providing radiation to an oral cavity and discloses that it has been found that there is antibacterial and anti-inflammatory action of UV (330-380 nm), blue (440-450 nm) and green (514-590 nm) radiation. In addition the red (630-640 nm) and near IR (830-1300 nm) radiation also provides prophylaxis and caries treating influence (Col. 2, lines 7-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the lower wavelengths as taught by Altshuler in the method of Biel '236 in view of Biel '3808 as Altshuler specifically teaches the benefits of using such wavelengths in radiation in an oral cavity.

Allowable Subject Matter

Claim 18 is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 3739

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 5:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Henry M. Johnson, III/
Primary Examiner, Art Unit 3739

/HMJ/
7/25/2008